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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/659,802

09/10/2003

Patrick Fogarty

TOSK-007CON

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24353 7590 09/15/2008  
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EXAMINER

MONTANARI, DAVID A

ART UNIT

PAPER NUMBER

1632

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DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/659,802	<b>Applicant(s)</b> FOGARTY, PATRICK	
	<b>Examiner</b> David Montanari	<b>Art Unit</b> 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 16 June 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 11, 13-15, 18, 27, 30, 31 and 34 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11, 13-15, 18, 27, 30, 31 and 34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

1. Applicants arguments and amendments filed on 6/16/2008 have been entered.
2. Claims 11, 13, 14, 27 and 31 are amended.
3. The objection of claim 11, 13 and 14 is withdrawn in view of Applicants amendments to the claims.
4. Claims 11, 13-15, 18, 27, 30, 31 and 34 are examined in the instant application.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11, 13-15, 18, 27, 30, 31 and 34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 11, 27 and 31 are newly amended and each recite "wherein said vector comprises a pair of P-element transposase recognized insertion sequences flanking a P-feet flanked domain of at least about 2,000 bp in length".

As the newly amended claims are written it is unclear if there are two sets of flanking P-feet.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 11, 13-15, 18, 27, 30, 31 and 34 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent 6,291,243 B1 (Fogarty et al.)

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention “by another,” or by an appropriate showing under 37 CFR 1.131.

Fogarty et al. teach that the P element vector can be used to insert exogenous or endogenous nucleic acids into the genomes of mammalian cells including rat and murine (col. 5 lines 42-59). Fogarty et al. teach and claim a method of inserting an exogenous nucleic acid into a non-insect target cell genome, including mouse and rat (col. 5 lines 42-59), using a P element derived vector ('243 claim 12). The P element derived vector comprises a pair of P element transposase recognition sites flanking at least two non-insect cell transcriptionally active expression modules each comprising a coding sequence and a promoter ('243 claim 1). The P element vector taught by Fogarty et al. further comprises that said transposase recognition sites

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are 31 base pair inverted repeats (claim 6). Fogarty et al. teaches that the P element vector comprises an inter P feet domain that is at least 50 bp in length, or usually at least 1000 bp in length corresponding to the nucleic acid to be inserted into the host genome (col. 4 lines 1-11). Fig. 2 (casper4) in the Fogarty patent demonstrates that the white gene is separated from the 5' P foot by a distance less than 1000 bp and that is also the case for the 3' P foot. Fig. 2 (casper4) clearly marks in increments of 1000 the relation of the transcriptionally active white gene and the P feet. This teaching by Fogarty anticipates that a single transcriptionally active gene is separated from a P element transposase domain by a distance of about 1000 bp or less. The claims in the Fogarty patent are drawn to a method of using a P element vector that comprises at least two non-insect cell genes flanked by a pair of P element transposase recognition sites, however Fogarty et al. in their specification teach that a single gene can be flanked by said transposase recognition sites (col. 5 lines 5-9). Fogarty et al. explicitly states that “ Vectors of this embodiment that include a single transcriptionally active gene may be prepared and used as described below, where the following description is provided in terms of vectors that include at least two transcriptionally active genes.” (col. 5 lines 5-9). Fogarty et al. (‘243 claim 14) further teach that a second vector can be delivered using the claimed method (as required by instant claim 14). With regard to the claimed rodent made by the claimed method, the prior art is enabling to the extent that a transgenic mouse is created using the claimed method and the method disclosed in the Fogarty patent. Fogarty teaches that the claimed method, which is a transformation method, can be used for the creation of transgenic animals, including rodents (col. 1 lines 16-28). Thus Fogarty et al. clearly anticipate the claimed method.

***Response to Arguments***

Applicants argue in amendment filed on 6/16/2008 that the claims require the presence of a P-feet flanked domain of at least 2000 bp comprising a transcriptionally active gene that is less than 1000 bp from one of the p-feet. Applicants continue that is element is not taught in the Fogarty patent. This argument is not persuasive.

Applicants in their arguments cite that pg. 8 lines 1-5 shows support for the new claim amendment. Pg. 8 lines 1-5 reads:

“Typically, the size of this inter P feet domain (i.e., P feet flanked domain) is at least about 50 bp in length, usually at least about 1,000 bp in length and more usually at least about 2,000 bp in length, Where the length of this domain may be as long as 150,000 bp or longer, but sometimes does not exceed about 50,000 bp in length and in certain embodiments does not exceed about 20,000 bp in length.”

In the Fogarty patent beginning with col. 4 lines 5-11 it reads:

“Typically, the size of this inter P feet domain (i.e. P feet flanked domain) is at least about 50 bp in length, usually at least about 1000 bp in length and more usually at least about 2000 bp in length, where the length of this domain may be as long as 150,000 bp or longer, but generally does not exceed about 20,000 bp in length and more usually does not exceed about 10,000 bp in length.”

In view of Applicants new amendment to the claims reciting that the P-feet flanked domain be at least 2,000 bp in length, the teachings above from the Fogarty patent would anticipate Applicants claimed invention.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Montanari whose telephone number is (571)272-3108.

The examiner can normally be reached on M-Tr 8-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on 1-571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Valarie Bertoglio/  
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